



**United States
General Accounting Office
Washington, D.C. 20548**

Office of the General Counsel

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July 9, 1998

The Honorable William V. Roth
Chairman
The Honorable Daniel Patrick Moynihan
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

**Subject: Department of Health and Human Services, Health Care Financing
Administration: Medicare Program; Medicare Coverage of and Payment
for Bone Mass Measurements**

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Health Care Financing Administration (HCFA), entitled "Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements" (RIN: 0938-AI89). We received the rule on June 25, 1998. It was published in the Federal Register as a final rule on June 24, 1998. 63 Fed. Reg. 34320.

The interim final rule with comment period provides for uniform coverage of, and payment for, bone mass measurements for certain Medicare beneficiaries for services furnished on or after July 1, 1998. The rule implements section 4106(a) of the Balanced Budget Act of 1997.

Enclosed is our assessment of HCFA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that HCFA complied with the applicable requirements.

If you have any questions about this report, please contact James Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the Department of Health and Human Services, Health Care Financing Administration, is William Scanlon, Director, Health Financing and Systems Issues. Mr. Scanlon can be reached at (202) 512-7114.

Robert P. Murphy
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala
The Secretary of Health and
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
ENTITLED
"MEDICARE PROGRAM; MEDICARE COVERAGE OF AND
PAYMENT FOR BONE MASS MEASUREMENTS"
(RIN: 0938-AI89)

(i) Cost-benefit analysis

HCFA performed a cost-benefit analysis of the rule and found that it will result in additional expenditures of \$10 million in fiscal year (FY) 1998, \$100 million in FY 1999, \$140 million in FY 2000, \$180 million in FY 2001, and \$190 million in FY 2002.

The expected benefit is that the effects of osteoporosis among the Medicare population will be reduced through earlier detection of low bone mass and the use of appropriate prevention and treatment measures.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

Under the Regulatory Flexibility Act, HCFA considers all physicians to be small entities. Since the interim final rule will result in additional Medicare payments to a large number of physicians, in addition to hospital outpatient departments, there will not be a significant adverse economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The interim final rule does not impose a federal intergovernmental or private sector mandate of \$100 million or more, as defined in the Unfunded Mandates Reform Act of 1995.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act (APA), 5 U.S.C. §§ 551 *et seq.*

This rule was issued as an interim final rule with comment period because the Secretary of Health and Human Services found "good cause" that notice and

comment procedures were unnecessary and contrary to the public interest. 5 U.S.C. § 553(b)(B). The rule conforms Medicare regulations to the requirements imposed by section 4106 of the Balanced Budget Act of 1997 and, according to HCFA, the rule involves little exercise of agency discretion. Likewise, the 30-day delay in the effective date of a rule under the APA, 5 U.S.C. § 553(d), was waived because it would delay implementation of this rule, which is designed to extend the benefits of bone mass measurement to Medicare beneficiaries.

Since there was neither a proposed rule nor the receipt of public comments, HCFA has properly invoked the exception found at 5 U.S.C. § 808(2) to the 60-day delay in the effective date of a major rule normally required under the Congressional Review subtitle of the Small Business Regulatory Enforcement Fairness Act of 1996.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The interim final rule does not contain any information collections which are subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

Statutory authorization for the rule

The interim final rule was promulgated pursuant to the authority in sections 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. §§ 1302, 1395hh, and 1395rr(b)(1)) and section 4106 of the Balanced Budget Act of 1997.

Executive Order No. 12866

The rule was found to be an "economically significant" regulatory action under Executive Order No. 12866 and was reviewed by the Office of Management and Budget.